- Oxacephem antibiotic agent -

**FLUMARIN®** for Intravenous Injection 0.5 g

**FLUMARIN®** for Intravenous Injection 1 g

**FLUMARIN®** Kit for Intravenous Injection 1 g

*FLUMARIN* for Intravenous Injection 0.5 g

*FLUMARIN* for Intravenous Injection 1 g

*FLUMARIN* Kit for Intravenous Injection 1 g

< The Japanese Pharmacopoeia Flomoxef sodium for injection >

prescription drug

<table>
<thead>
<tr>
<th>Ingredient / content (Content per vial or kit)</th>
<th>0.5 g for IV Inj.</th>
<th>1 g for IV Inj.</th>
<th>1 g Kit for IV Inj.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flomoxef sodium 0.5 g (potency)</td>
<td>Flomoxef sodium 1 g (potency)</td>
<td>Flomoxef sodium 1 g (potency)</td>
<td></td>
</tr>
<tr>
<td>Sodium chloride 25 mg</td>
<td>Sodium chloride 50 mg</td>
<td>Sodium chloride 50 mg</td>
<td></td>
</tr>
</tbody>
</table>

**Description**

1. Composition

<table>
<thead>
<tr>
<th>Brand name</th>
<th>FLUMARIN® for IV Inj. 0.5 g</th>
<th>FLUMARIN® for IV Inj. 1 g</th>
<th>FLUMARIN® Kit for IV Inj. 1 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>A white to light yellowish white, light mass or powder (Injection)</td>
<td>A white to light yellowish white, light mass or powder (Injection)</td>
<td>A white to light yellowish white powder (Injection)</td>
</tr>
<tr>
<td>pH</td>
<td>4.0-5.5</td>
<td>4.0-5.5</td>
<td>4.0-6.0</td>
</tr>
<tr>
<td>100 mg (potency) / mL aqueous solution</td>
<td>100 mg (potency) / mL aqueous solution</td>
<td>1 g (potency) / 100 mL isotonic sodium chloride solution</td>
<td></td>
</tr>
<tr>
<td>Osmotic pressure ratio</td>
<td>Approx. 2</td>
<td>Approx. 2</td>
<td>Approx. 1</td>
</tr>
<tr>
<td>(to isotonic sodium chloride solution)</td>
<td>mL isotonic sodium chloride solution</td>
<td>/100 mL isotonic sodium chloride solution</td>
<td></td>
</tr>
</tbody>
</table>

| Attached dissolving solution (Content per kit) | - | - | Japanese pharmacopoeia (JP) isotonic sodium chloride solution 100 mL |

**Product description**

<table>
<thead>
<tr>
<th>Brand name</th>
<th>FLUMARIN® for IV Inj. 0.5 g</th>
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<td>/100 mL isotonic sodium chloride solution</td>
<td></td>
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</table>

Kit: An injectable form in a plastic container with two chambers separated by a partition, the upper chamber filled with flomoxef sodium and the lower one filled with dissolving solution.

**Indications**

*Susceptible strains>*

Flomoxef sodium susceptible strains of *Staphylococcus* sp., *Streptococcus* sp., *Neisseria gonorrhoeae*, *Moraxella* (Branhamella) *catarrhalis*, *Escherichia coli*, *Klebsiella* sp., *Proteus* sp., *Morganella morgani*, *Providencia* sp., *Haemophilus influenzae*, *Peptostreptococcus* sp., *Bacteroides* sp., *Prevotella* sp. (excluding *Prevotella bivia*)

*Indications>*

- Septicemia, infectious endocarditis
- (Superficial) secondary infections in trauma, burns, surgical wounds, etc.
- Pharyngolaryngitis, tonsillitis, acute bronchitis, secondary infections in chronic respiratory diseases
- Cystitis, pyelonephritis, prostatitis (acute, chronic)
- Urethritis
- Peritonitis, intraabdominal abscess
- Cholecystitis, cholangitis
- Bartholinitis, intrauterine infection, uterine adenexitis, parametritis
• Otitis media, sinusitis

**DOSAGE AND ADMINISTRATION**

1. **FLUMARIN® for Intravenous Injection 0.5 g and FLUMARIN® for Intravenous Injection 1 g**
   Usually, for adults, 1-2 g (potency) of flomoxef sodium daily is injected or infused intravenously in 2 divided doses.
   Usually, for children, 60-80 mg (potency)/kg daily is injected or infused intravenously in 3 to 4 divided doses.
   Usually, for premature infants and neonates, a dose of 20 mg (potency)/kg is injected or infused intravenously 2-3 times daily within 3 days after birth and 3-4 times daily from the 4th day after birth.
   The dosage should be adjusted according to the age of patient and severity of the symptoms. In refractory or severe infections, the dose may be increased to 4 g (potency) daily in 2 to 4 divided doses for adults, and 150 mg (potency)/kg daily in 3 to 4 divided doses for premature infants, neonates and children.

2. **FLUMARIN® Kit for Intravenous Injection 1 g**
   Usually, for adults, 1-2 g (potency) of flomoxef sodium daily is infused intravenously in 2 divided doses.
   Usually, for children, 60-80 mg (potency)/kg daily is infused intravenously in 3 to 4 divided doses.
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For reference: Preparation of injectable solution

1. **FLUMARIN® for Intravenous Injection 0.5 g (potency) and 1 g (potency) each in 10 mL vial.**
   This product should be dissolved by shaking well after addition of not less than 4 mL of water for injection, 5% glucose solution for injection or isotonic sodium chloride solution. When this product is infused intravenously, water for injection must not be used as solvent, because, with water for injection, this product doesn’t become isotonic.

2. **FLUMARIN® Kit for Intravenous Injection 1 g (potency)**
   Flomoxef sodium should be dissolved in the attached dissolving solution by pressing on the side of the bag where the dissolving solution (isotonic sodium chloride solution (JP)) is filled, to break the partition between the drug and dissolving solution, and then pressing repeatedly on the bag to reconstitute the drug substance thoroughly. (For further details, refer to “Dissolution Procedure” printed on the outer plastic packaging and aluminum cover sheet of the kit product.)

**PRECAUTIONS**

1. **Careful Administration (FLUMARIN® should be administered with care in the following patients.)**
   (1) For the use of vial and kit product
   1) Patients with a history of hypersensitivity to penicillins
   2) Patients with a personal or familial predisposition to allergic reactions such as bronchial asthma, rash and urticaria
   3) Patients with severe renal dysfunction [Since blood concentrations of this product are maintained for long duration, the product should be administered with dosage adjustment such as reduction of the dose or prolonging dose interval. (See “PHARMA-COKINETICS” section)]
   4) Patients of poor oral ingestion, patients receiving parenteral feeding, or patients in poor general condition [Since vitamin K deficiency symptoms may occur, patients should be carefully observed.]
   5) Elderly patients [See “Use in the Elderly” section]
   (2) For the use of kit product only
   1) Patients with cardiac or circulatory dysfunction [Since increased sodium load and circulatory blood volume on their hearts may put a strain, dysfunction symptoms may be worsened.]
   2) Patients with renal dysfunction [Dysfunction symptoms may be aggravated, retention of fluid and sodium chloride may be facilitated.]

2. **Important Precautions**
Since there is no way of predicting the development of shock or anaphylactoid reaction by this product properly, the following measures should be taken:
   (1) The patients should be carefully interviewed about previous history, etc. prior to use. A history of allergy to antibiotics, etc. should surely be confirmed.
   (2) Emergency facilities should surely be prepared beforehand for development of shock, etc.
   (3) From the beginning of administration to after the end of administration of this product, patients should be kept at rest and under adequate supervision. The patients should be observed especially carefully immediately after the beginning of administration.

3. **Drug Interactions**
4. Adverse Reactions

Out of 3,314 cases evaluated for safety before approval and at the latest approval of indication, adverse reactions were observed in 78 cases (2.35%). In addition, out of 3,054 cases evaluated for safety by conducting laboratory tests, abnormal changes in the laboratory values were observed in 334 cases (10.94%).

Out of 27,651 cases evaluated for safety at the end of the re-examination period, adverse reactions including abnormal changes in laboratory values were observed in 810 cases (2.93%). In addition, out of 3,054 cases evaluated for safety by conducting laboratory tests, abnormal changes in laboratory values were observed in 334 cases (10.94%).

(The frequency of adverse reaction is based upon the results of analysis at the time of approvals, latest reexaminations and spontaneously submitted reports.)

(1) Clinically significant adverse reactions

1) Shock, anaphylactoid reaction (≤ 0.1%): Since shock or anaphylactoid reaction (dyspnea, generalized flushing, edema, etc.) may occur, patients should be closely observed. If any symptom occurs, the therapy should be discontinued and appropriate measures should be taken.

2) Acute renal failure (≤ 0.1%): Since serious renal impairment such as acute renal failure may occur, patients should be closely observed by periodically conducting laboratory tests. If any abnormality is observed, the therapy should be discontinued and appropriate measures should be taken.

3) Pancytopenia, agranulocytosis (≤ 0.1%), thrombocytopenia, hemolytic anemia (Incidence unknown): Pancytopenia, agranulocytosis, thrombocytopenia or hemolytic anemia may occur. If any abnormality is observed, the therapy should be discontinued and appropriate measures should be taken.

4) Pseudomembranous colitis (≤ 0.1%): Serious colitis with bloody stools such as pseudomembranous colitis may occur. If abdominal pain or frequent diarrhea occurs, appropriate measures such as immediate discontinuation of this product should be taken.

5) Muco-cutaneous-ocular syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis (Lyell syndrome) (≤ 0.1%): Muco-cutaneous-ocular syndrome (Stevens-Johnson syndrome) or toxic epidermal necrolysis (Lyell syndrome) may occur. Patients should be carefully observed, and if such symptoms occur, the therapy should be discontinued and appropriate measures should be taken.

6) Interstitial pneumonia, PIE syndrome (< 0.1%): Interstitial pneumonia, PIE syndrome, etc., accompanied with fever, cough, dyspnea, abnormal chest X-ray findings, eosinophilia, etc. may occur. If such symptoms occur, the therapy should be discontinued and appropriate treatment such as corticosteroid therapy should be taken.

7) Hepatic dysfunction, jaundice (Incidence unknown): Increases in SGOT (AST), SGPT (ALT), Al-P, gamma-GTP and LAP or jaundice may occur, patients should be closely observed by periodically conducting laboratory tests. If any abnormality is observed, the therapy should be discontinued and appropriate measures should be taken.

(2) Other adverse reactions

<table>
<thead>
<tr>
<th>Incidence</th>
<th>Body system</th>
<th>5% &gt;</th>
<th>≤ 0.1%</th>
<th>&lt; 0.1%</th>
<th>Incidence unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypersensitivity</td>
<td>Rash</td>
<td>Urticaria, pruritus, redness, fever, facial hot flushes, skin paraesthesia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematologic</td>
<td>Anemia (decreased RBC, decreased hemoglobin, decreased hematocrit, eosinophilia, granulocytopenia)</td>
<td>Thrombocytopenia or thrombocytosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal</td>
<td>Increased BUN, increased creatinine, proteinuria</td>
<td>Oliguria</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatic</td>
<td>Increased SGOT (AST), increased SGPT (ALT), increased Al-P, increased gamma-GTP</td>
<td>Jaundice, increased LAP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>Diarrhea</td>
<td>Soft stools, nausea, vomiting, feeling of enlarged abdomen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microbial substitution</td>
<td>Stomatitis, candidiasis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypovitaminosis</td>
<td>Vitamin K deficiency symptoms (hyperprothrombinemia, bleeding tendency, etc.), vitamin B complex deficiency symptoms (glossitis, stomatitis, anorexia, neuritis, etc.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>Dull headache, generalized malaise, strange sensation of urethra, increased serum amylase, increased urinary amylase</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note 1) If any symptom (abnormality) is observed, the therapy should be discontinued and appropriate measures should be taken.
Note 2) If any abnormality is observed, appropriate measures such as discontinuation should be taken.

5. Use in the Elderly
This product should be carefully administered to elderly patients with attention to the following points, and the dose and administration interval should be considered under a close clinical observation of the patient’s conditions.
(1) Since the elderly often have reduced physiological functions, adverse reactions tend to occur more frequently.
(2) In elderly patients, bleeding tendency due to vitamin K deficiency may occur.

6. Use during Pregnancy, Delivery or Lactation
This product should be administered to women who are or may become pregnant only if the expected therapeutic benefits are evaluated to exceed any possible risk associated with treatment. [The safety of this product in pregnant women has not yet been established.]

7. Pediatric Use
This product should be administered with care in low birth weight infants (premature infants) because high blood concentration may persist for a long period due to the prolongation of the blood concentration half-life caused by the immature kidney. [See “< Precautions >” in “DOSEAGE AND ADMINISTRATION” and “PHARMACOKINETICS” section]

8. Effects on Laboratory Tests
(1) Since false-positive results may occur in urine sugar tests with Benedict’s solution. Fehling’s solution and Clinitest except Tes-Tape, caution should be paid.
(2) Care should be taken about positive reactions in the direct Coombs’ test.

9. Precautions concerning Use
(1) Preparation: This product should be used immediately after reconstitution. If the reconstituted drug is stored by necessary, it should be used within 6 hours when stored at room temperature, or within 24 hours when stored in a refrigerator.
For the kit product, residual solution must not be used in any way.
(2) Caution in intravenous administration: As high intravenous doses may cause vascular pain, phlebitis or burning sensation, care should be taken about preparation of the injection solution, injection site, injection method, etc., and the rate of injection should be as slow as possible to avoid such complication.

10. Other Precautions
It is desirable that periodic examinations of liver function, renal function, blood, etc. are conducted during administration of this drug.

PHARMACOKINETICS
1. Blood concentration
(1) Healthy adults\(^1\) (Serum concentrations and pharmacokinetic parameters after IV injection or during/after IV infusion)

<table>
<thead>
<tr>
<th>Sign</th>
<th>Dose [g (potency)]</th>
<th>C(_{\text{max}}) ((\mu\text{g} / \text{mL}))</th>
<th>T(_{1/2}) ((\beta)) (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>▲</td>
<td>0.5</td>
<td>4</td>
<td>39.4</td>
</tr>
<tr>
<td>●</td>
<td>1</td>
<td>22</td>
<td>126.2</td>
</tr>
</tbody>
</table>
(analytical method: bioassay) (mean)
Note 1) Serum concentrations (values 5 minutes after administration)

1-hr. IV infusion

<table>
<thead>
<tr>
<th>Sign</th>
<th>Dose [g (potency)]</th>
<th>C(_{\text{max}}) ((\mu\text{g} / \text{mL}))</th>
<th>T(_{1/2}) ((\beta)) (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>▲</td>
<td>0.5</td>
<td>4</td>
<td>19.6</td>
</tr>
<tr>
<td>●</td>
<td>1</td>
<td>25</td>
<td>44.0</td>
</tr>
<tr>
<td>○</td>
<td>2</td>
<td>10</td>
<td>89.5</td>
</tr>
</tbody>
</table>
(2) Children with normal renal function\(^3\) (Serum concentrations and pharmacokinetic parameters after IV injection or during/after IV infusion)
(3) Low birth weight infants (premature infants) and neonates (Plasma concentrations and pharmacokinetic parameters after IV injection)

(4) Patients with renal impairment (Serum concentrations and pharmacokinetic parameters after IV injection)

Prolongation of blood half-life and retardation of urinary excretion were observed with the decrease of renal function. Therefore, adequate adjustments of the dose and administration interval are necessary for administration to patients with renal impairment.
PHARMACOLOGY

1. Pharmacological activity

Antibacterial activity

Flomoxef sodium shows a broad spectrum of antibacterial activity in vitro against gram-positive and gram-negative bacteria, including both aerobes and anaerobes. Flomoxef sodium demonstrates antibacterial activity against gram-positive microorganisms such as Staphylococcus sp., Streptococcus sp., Pneumococcus sp. Flomoxef sodium demonstrates antibacterial activity against gram-negative microorganisms such as Neisseria gonorrhoeae, Moraxella (Branhamella) catarrhalis, Escherichia coli, Klebsiella sp., Proteus sp., Morganella morganii, Providencia sp. and Haemophilus influenzae. Flomoxef sodium also demonstrates antibacterial activity against anaerobes such as Peptostreptococcus sp., Bacteroides sp. and Prevotella sp. (excluding Prevotella bivia). In addition, it is stable toward β-lactamases produced by various microorganisms. 12, 13

2. Mechanism of action

The antibacterial action of flomoxef sodium results from the inhibition of bacterial cell wall synthesis, and this action is bactericidal. Flomoxef sodium has binding-affinity for penicillin-binding proteins (PBP), and demonstrates antibacterial activity, especially by showing inhibiting action to murein-crosslinking enzymes. Besides, flomoxef sodium is characterized by its scarce inactivation by β-lactamases produced by various microorganisms.

CLINICAL STUDIES

In open clinical studies performed before NDA approval and at the latest approval of indication, the number of cases evaluated for efficacy was 1,513 cases, and the efficacy rate was 74.0% (1,120 cases). 13

Table 8: Clinical studies

<table>
<thead>
<tr>
<th>Disease</th>
<th>No. of “effective” cases / No. of cases evaluated for efficacy</th>
<th>Efficacy rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Septicemia, infectious endocarditis (Superficial) secondary infections in trauma, burns, surgical wounds, etc.</td>
<td>20/26</td>
<td>76.9</td>
</tr>
<tr>
<td>Pharyngolaryngitis, tonsillitis, acute bronchitis</td>
<td>31/45</td>
<td>68.9</td>
</tr>
<tr>
<td>Secondary infections in chronic respiratory diseases</td>
<td>136/145</td>
<td>93.8</td>
</tr>
<tr>
<td>Cystitis, Pyelonephritis</td>
<td>79.2</td>
<td></td>
</tr>
<tr>
<td>Prostatitis (acute, chronic)</td>
<td>19/20</td>
<td>95.0</td>
</tr>
<tr>
<td>Peritonitis, intraabdominal abscess</td>
<td>102/125</td>
<td>81.6</td>
</tr>
<tr>
<td>Cholecystitis, cholangitis</td>
<td>61/85</td>
<td>71.8</td>
</tr>
<tr>
<td>Bartholinis</td>
<td>25/26</td>
<td>96.2</td>
</tr>
<tr>
<td>Intrauterine infection</td>
<td>87/96</td>
<td>90.6</td>
</tr>
<tr>
<td>Uterine adenitis</td>
<td>40/44</td>
<td>90.9</td>
</tr>
<tr>
<td>Parametritis</td>
<td>29/30</td>
<td>96.7</td>
</tr>
<tr>
<td>Otitis media</td>
<td>26/47</td>
<td>55.3</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>29/39</td>
<td>74.4</td>
</tr>
</tbody>
</table>

(5) Patients on hemodialysis 13 (Serum concentrations and pharmacokinetic parameters after IV injection)

2. Distribution

Flomoxef sodium showed good transfer into the following body fluid and tissues:
- Bile 3
- Sputum 3
- Intraperitoneal exudates 3
- Intrapelvic dead space exudates 3
- Gallbladder 3
- Uterus 3
- Adnexa uteri 3
- Mucosa of the middle ear 8
- Lung tissues 3
- Etc. In lactating mothers (n=5), the average concentration in breast milk was 0.5 μg/mL or less after an intravenous injection of 1 g (potency) of this product. 9

3. Metabolism

Flomoxef sodium is metabolized very little in the body, and the majority of the drug (80-90%) at 12 hours after administration is excreted into the urine as unchanged form.

Flomoxef oxide as an active metabolite and hydroxy-ethyltetrazolethiol (HTT) as an inactive metabolite demonstrates antibacterial activity against anaerobes such as Peptostreptococcus sp., Bacteroides sp. and Prevotella sp. (excluding Prevotella bivia). In addition, it is stable toward β-lactamases produced by various microorganisms.

4. Excretion

Flomoxef sodium is excreted mainly from the kidney. Independent of the dose, the urinary excretion rates on the average were 50-70% up to 2 hours and 80-90% up to 12 hours, respectively, in healthy adults administered a dose of 0.5 g (potency) (n=4) or 1 g (potency) (n=4) by IV injection, a dose of 1 g (potency) (n=13) or 2 g (potency) (n=10) by IV infusion for 1 hour, or a dose of 0.5 g (potency) (n=3), 1 g (potency) (n=4) or 2 g (potency) (n=4) by IV infusion for 2 hours. 10

5. Others

Serum protein binding rate: Serum protein binding rate was 35%, measured by ultrafiltration. 11

Table 7: Pharmacokinetic parameters

<table>
<thead>
<tr>
<th>Creatinine clearance</th>
<th>n</th>
<th>T1/2 (β) (hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>9.62</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>6.95</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>2.48</td>
</tr>
<tr>
<td>4</td>
<td>10</td>
<td>1.57</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>1.31</td>
</tr>
</tbody>
</table>

(α-lactamase production: bioassay, HPLC) (mean)

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- Etc. In lactating mothers (n=5), the average concentration in breast milk was 0.5 μg/mL or less after an intravenous injection of 1 g (potency) of this product. 9

3. Metabolism

Flomoxef sodium is metabolized very little in the body, and the majority of the drug (80-90%) at 12 hours after administration is excreted into the urine as unchanged form.

Flomoxef oxide as an active metabolite and hydroxy-ethyltetrazolethiol (HTT) as an inactive metabolite have been confirmed, and their urinary recovery rates at 24 hours were 0.1-0.3% and 10-23%, respectively. 10

4. Excretion

Flomoxef sodium is excreted mainly from the kidney. Independent of the dose, the urinary excretion rates on the average were 50-70% up to 2 hours and 80-90% up to 12 hours, respectively, in healthy adults administered a dose of 0.5 g (potency) (n=4) or 1 g (potency) (n=4) by IV injection, a dose of 1 g (potency) (n=13) or 2 g (potency) (n=10) by IV infusion for 1 hour, or a dose of 0.5 g (potency) (n=3), 1 g (potency) (n=4) or 2 g (potency) (n=4) by IV infusion for 2 hours. 10

5. Others

Serum protein binding rate: Serum protein binding rate was 35%, measured by ultrafiltration. 11

Table 7: Pharmacokinetic parameters

<table>
<thead>
<tr>
<th>Creatinine clearance</th>
<th>n</th>
<th>T1/2 (β) (hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>9.62</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>6.95</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>2.48</td>
</tr>
<tr>
<td>4</td>
<td>10</td>
<td>1.57</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>1.31</td>
</tr>
</tbody>
</table>

(α-lactamase production: bioassay, HPLC) (mean)
PHYSICOCHEMISTRY

Nonproprietary name: Flomoxef Sodium
(JAN) (Japanese pharmacopoeia)

Abbreviation: FMOX

Chemical name:
Monosodium(6R,7R)-7-[[2-(difluoromethylsulfanyl)acetyl]amino]-3-[1-(2-hydroxyethyl)-1H-tetrazol-5-ylsulfanylmethyl]-7-methoxy-8-oxo-5-oxa-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate

Molecular formula: C_{15}H_{17}F_{2}N_{6}NaO_{7}S_{2}
Molecular weight: 518.45

Molecular structure:

Sodium content:
1 g (potency) of flomoxef sodium contains 46.3 mg (2.0 mEq) of sodium.

As preparations, FLUMARIN® 0.5 g and FULMARIN® 1 g contain 33.0 mg (1.4 mEq) and 66.0 mg (2.9 mEq), respectively, of sodium.

Description:
Flomoxef Sodium occurs as white to light yellowish white, powder or masses.
It is very soluble in water, freely soluble in methanol, and sparingly soluble in ethanol (99.5).

Melting point: 100-150°C (decomposition)
Partition coefficient: 0.001 (1-octanol/water system)

PRECAUTIONS FOR HANDLING

Attention should be paid to the following points when handling the kit product.

1. To preserve the quality of the product, the seal on the outer bag should not be broken until just before use.
2. The product should not be used in the following cases.
   (1) The outer bag is torn or the dissolving solution is leaked.
   (2) The drug has already been dissolved before breaking the partition.
   (3) The drug has become discolored or the dissolving solution is no longer colorless before reconstitution.
3. The scale on the container should be used only as a rough standard.

PACKAGING

FLUMARIN® for Intravenous Injection 0.5 g:
10 vials (10 mL vial)
FLUMARIN® for Intravenous Injection 1 g:
10 vials (10 mL vial)
FLUMARIN® Kit for Intravenous Injection 1 g:
10 kits

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